

Promoting public awareness of randomised clinical trials using the media: the 'Get Randomised' campaign

Isla S. Mackenzie, Li Wei, Daniel Rutherford, Evelyn A. Findlay, Wendy Saywood, Marion K. Campbell¹ & Thomas M. MacDonald

Medicines Monitoring Unit (MEMO), University of Dundee, Dundee and ¹Health Services Research Unit, University of Aberdeen, Aberdeen, UK

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Recruitment is key to the success of clinical trials.
- Many clinical trials fail to achieve adequate recruitment.
- Public understanding and engagement in clinical research could be improved.

WHAT THIS STUDY ADDS

- 'Get Randomised' is the first campaign of its kind in the UK.
- It is possible to improve public awareness of clinical research using the media.
- Further work is needed to determine whether improved public awareness leads to increased participation in clinical research in the future.

Correspondence

Dr Isla S. Mackenzie, Medicines Monitoring Unit (MEMO), University of Dundee, Level 7 Ninewells Hospital, Dundee DD1 9SY, UK.
Tel: +44 1382 632575
Fax: +44 1382 740209
E-mail: i.s.mackenzie@dundee.ac.uk

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AIM

To increase public awareness and understanding of clinical research in Scotland.

METHODS

A generic media campaign to raise public awareness of clinical research was launched in 2008. The 'Get Randomised' campaign was a Scotland-wide initiative led by the University of Dundee in collaboration with other Scottish universities. Television, radio and newspaper advertising showed leading clinical researchers, general practitioners and patients informing the public about the importance of randomised clinical trials (RCTs). 'Get Randomised' was the central message and interested individuals were directed to the <http://www.getrandomised.org> website for more information. To assess the impact of the campaign, cross-sectional surveys were conducted in representative samples of 1040 adults in Scotland prior to campaign launch and again 6 months later.

RESULTS

There was an improvement in public awareness of clinical trials following the campaign; 56.7% [95% confidence interval (CI) 51.8, 61.6] of the sample recalled seeing or hearing advertising about RCTs following the campaign compared with 14.8% (10.8, 18.9) prior to the campaign launch (difference = 41.4%; 95% CI for difference 35.6, 48.3; $P < 0.01$). Of those who recalled the advertising, 49% felt that the main message was that people should take part more in medical research. However, on whether they would personally take part in a clinical trial if asked, there was little difference in response following the campaign ['yes' 31.3% (28.4, 34.1) prior; 30.4% (27.6, 33.2) following; difference = -0.9%; 95% CI for difference -4.8, 3.1%; $P = 0.92$].

CONCLUSIONS

It is possible to raise public awareness of clinical research using the media, but further efforts may be required to influence individuals' decisions to take part in clinical research.

Introduction

Clinical trials rely on adequate recruitment in order to achieve their clinical and scientific aims. However, a recent review of recruitment into UK trials showed that less than one-third of trials recruited to target within the originally specified time period and around one-third required extensions to allow adequate recruitment [1]. A similar picture of poor recruitment was found in a survey of UK primary care trials [2]. Failure to achieve recruitment within a reasonable time period adds expense and logistical difficulties to clinical research and may result in failure to answer the question that the trial was originally designed to address. Also, poor recruitment delays the availability of the results of the trial to inform clinical practice decisions. Although many different factors interplay to determine the level of recruitment into any one clinical trial, a key factor is the initial engagement of potential patient recruits to consider participation in the trial.

Current public understanding of clinical research is poor and media coverage of clinical research trials is often negative [3]. With the aim of increasing public awareness and understanding of clinical research in Scotland and ultimately increasing public engagement in clinical trials, we launched a generic media campaign in August 2008—the 'Get Randomised' campaign (Figure 1). This was a Scotland-wide initiative led by the University of Dundee in collaboration with the Universities of Aberdeen, Edinburgh and Glasgow. Television, radio and newspaper advertising showed leading clinical researchers, general practitioners and patients informing the public about the importance of randomised clinical trials (RCTs). Interested individuals were directed to a dedicated website (<http://www.getrandomised.org>) to obtain more information.

In order to assess the impact of the 'Get Randomised' campaign on public awareness of clinical research in Scotland, a survey was conducted in the Scottish general public prior to the campaign launch and again after 6 months. Participants were asked questions about their views on

and knowledge of RCTs and clinical research, whether they had seen any recent advertising about clinical trials and how the advertising had influenced them.

Methods

The 'Get Randomised' campaign was designed and initiated by investigators at the University of Dundee. The generic campaign was not linked to any particular research study but rather aimed to increase general public awareness of clinical research in Scotland. The content of the campaign was reviewed by the Scottish Research Ethics committee and was judged not to require formal ethical approval. Television, radio and newspaper advertising were used in the campaign. Television advertisements including leading researchers, general practitioners and patients talking about clinical research were shown on Scottish Television (Figure 2). Advertisements were regionalized with four different versions to include local researchers and patients. Advertisements were mainly 30 s in duration but some shorter versions lasting 10 s were also included. Around 200 television advertisements were broadcast over a 3-month period. Audio recordings with similar content were played on local and national Scottish radio stations and advertisements were placed in local and national Scottish newspapers (Figure 3). The campaign ran for 3 months and the initial budget for the production and airtime of the television advertisements was £80 000. Broad coverage of the whole adult population was the aim of the campaign.

A 'GetRandomised' website, <http://www.getrandomised.org>, was established to allow interested individuals to access further information about clinical research and trial design (Figure 4). The website includes links to other useful websites with information on clinical research. Examples of the advertisements are available to view on the website.



Figure 1

The logo for the 'Get Randomised' campaign was designed to depict the message that people of all ages can participate in clinical research



Figure 2

Television advertising included leading researchers, general practitioners and patients talking about the importance of clinical research. Here, Dr Alex Watson (General Practitioner, Westgate Health Centre, Dundee, UK) explains the importance of randomised clinical trials



Figure 3

Newspaper advertisements directed readers to the website for more information

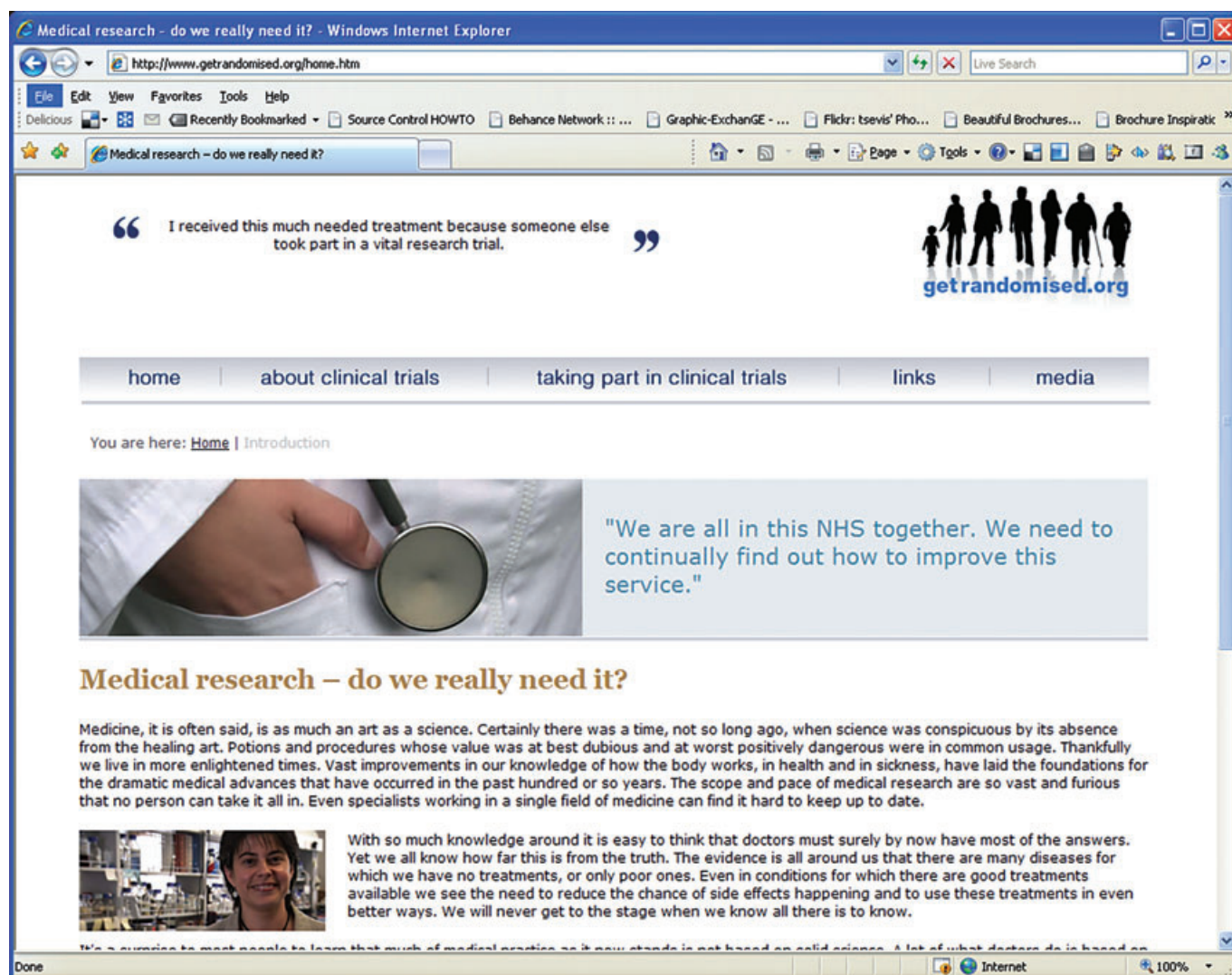


Figure 4

The 'Get Randomised' website <http://www.getrandomised.org> contains information about randomised clinical trials and links to other sources of information about clinical research

Table 1

Population distribution by age and gender in the two surveys

Age group (years)	Survey 1			Survey 2		
	Male n (%)	Female n (%)	Total n (%)	Male n (%)	Female n (%)	Total n (%)
16–24	81 (15.9)	96 (18.1)	177 (17.0)	70 (13.5)	77 (14.8)	147 (14.1)
25–34	92 (18.0)	77 (14.5)	169 (16.3)	91 (17.5)	87 (16.7)	178 (17.1)
35–44	94 (18.4)	101 (19.1)	195 (18.8)	107 (20.6)	89 (17.1)	196 (18.8)
45–54	83 (16.3)	82 (15.5)	165 (15.9)	92 (17.7)	86 (16.5)	178 (17.1)
55–64	67 (13.1)	82 (15.5)	149 (14.3)	54 (10.4)	79 (15.2)	133 (12.8)
65+	93 (18.2)	92 (17.4)	185 (17.8)	106 (20.4)	102 (19.6)	208 (20.0)
Total	510 (100.0)	530 (100.0)	1040 (100.0)	520 (100.0)	520 (100.0)	1040 (100.0)

Public awareness and understanding of clinical research before and after the 'Get Randomised' campaign was measured by conducting surveys with members of the public. The surveys (Survey 1 before the campaign; Survey 2 6 months after the start of the campaign) were conducted by mruk research (Manchester, UK) as part of a monthly Scottish Consumer Omnibus Survey. Two thousand and eighty people took part in the surveys (1040 different people at each survey). This sample size allowed proportions to be estimated within a margin of error of 3%. The structured sample was representative of the adult Scottish population in gender and age distribution (Table 1) and geographical spread. Participants were not asked whether they had any personal health problems as part of the survey, but the health of the survey population was likely to be representative of that of the adult Scottish population. Interviews were conducted between 8 and 14 August 2008 (Survey 1) and between 16 and 22 January 2009 (Survey 2). The questions included in the pre- and post-campaign surveys are listed in Table 2.

Data are reported as percentages with 95% confidence intervals (CI) where appropriate. Differences in proportions were analysed using χ^2 tests.

Results

There was an improvement in public awareness of clinical trials following the campaign. The phrase 'randomised clinical trial' had been heard of by 37.8% of people (95% CI 34.8, 40.7) in the second survey compared with 28.6% (95% CI 25.8, 31.3) in the first survey (difference = 9.2%; 95% CI for difference 5.2, 13.3, $P < 0.01$). The increased awareness was across both genders and all age groups (Figures 5 and 6).

Knowledge of aspects of RCTs such as the fact that 'all age groups are needed to take part in clinical trials' and 'we all need treatment at some point and trials tell us about the best treatments' increased from 4.7% (95% CI 2.3, 7.1) and 2.4% (95% CI 0.6, 4.1) in the first survey to 16.5% (95% CI 12.9, 20.2) and 8.4% (95% CI 5.6, 11.1) in the second survey, respectively ($P < 0.01$) (Table 3).

Over half of people of both sexes and of all age groups in the second survey recalled seeing or hearing any advertising recently about RCTs [56.7% (95% CI 51.8, 61.6)], compared with 14.8% (95% CI 10.8, 18.9; difference = 41.4%; 95% CI for difference 35.6, 48.3; $P < 0.01$) in the first survey. When asked where they recalled seeing or hearing such advertising, the most commonly reported media source was television (91%) followed by newspaper (8%) and radio (8%). Other places they reported seeing advertising about RCTs included posters (4%) and magazines (1%). These figures may have included other sources of advertising regarding clinical trials apart from the 'Get Randomised' campaign.

When asked to describe the activity or publicity they saw, 48% described health professionals speaking about medical research, 28% described health professionals asking the public to take part in medical research and 17% described patients speaking about medical research. Sixteen percent mentioned medical research or clinical trials in a less specific manner, 15% described the 'Get Randomised' message and 13% mentioned that the best evidence comes from RCTs. Eleven percent could not recall the content of the advertising they had seen or heard.

Forty-nine percent of respondents described the main message of the publicity as 'people should take part more in medical research'. Other main messages reported included 'doctors need to do research called randomised clinical trials' (27%), 'more medical research is needed all the time' (24%), 'Get Randomised' (14%), 'the best medical research is called a randomised clinical trial' (12%). One percent reported that the advertisement was too short and they did not understand it, while 8% gave other answers.

Participants were asked to what extent they agreed with a series of statements regarding whether the advertising had made them think or behave differently regarding clinical trials and whether it had improved their understanding of clinical trials (Q4 in Survey 1 and Q7 in Survey 2). The proportion of people who disagreed a lot with these statements decreased from a range of 9.1–20.5% in the first survey to 1.3–4.9% in the second survey.

Table 2

Questions included in the pre- and post-campaign surveys

Pre-campaign survey (Survey 1)
Q1: Have you heard of the phrase 'randomised clinical trials'? Yes (go to Q2), No, Don't know (go to Q3)
Q2: If yes, what does it mean?
Q3: Have you seen or heard any advertising recently about randomised clinical trials? Yes (go to Q4), No, Don't know (go to Q5)
Q4: SHOWCARD – 'I'm now going to show you a list of statements and I'd like you to tell me to what extent you agree or disagree with each' A – The advertising which I saw or heard made me think or behave differently about taking part in clinical trials in the future B – The advertising which I saw or heard made me think differently about the importance of clinical trials C – The advertising which I saw or heard gave me a better understanding of what a randomised clinical trial is D – The advertising which I saw or heard made me more likely to take part in clinical trials in the future (Agree a lot; Agree a little; Neither agree nor disagree; Disagree a little; Disagree a lot; Don't know)
Q5: SHOWCARD – 'I'm now going to show you a list of statements and I'd like you to tell me to what extent you agree or disagree with each' A – It is important for everyone to take part in a randomised clinical trial if they are asked B – Taking part in clinical trials is as valuable to the NHS as giving blood C – I would take part in a randomised clinical trial if I was asked D – Taking part in clinical trials is only important if you are ill yourself E – I would recommend taking part in clinical trials to my friends and family if they asked me what I thought F – I am interested in finding out more about taking part in clinical trials (Agree a lot; Agree a little; Neither agree nor disagree; Disagree a little; Disagree a lot; Don't know)
Post-campaign survey (Survey 2)
Q1: Have you heard of the phrase 'randomised clinical trials'? Yes (go to Q2), No, Don't know (go to Q8)
Q2: If yes, what does it mean?
Q3: Have you seen or heard any advertising recently about randomised clinical trials? Yes (go to Q4), No, Don't know (go to Q8)
Q4: Where did you see it or hear it?
Q5: Please describe the activity or publicity you saw/heard concerning randomised clinical trials. What did it show/what did it say? (more than one response allowed)
Q6: What was the main message(s) of this activity/publicity? (more than one response allowed)
Q7: SHOWCARD – 'I'm now going to show you a list of statements and I'd like you to tell me to what extent you agree or disagree with each' A – The advertising which I saw or heard made me think or behave differently about taking part in clinical trials in the future B – The advertising which I saw or heard made me think differently about the importance of clinical trials C – The advertising which I saw or heard gave me a better understanding of what a randomised clinical trial is D – The advertising which I saw or heard made me more likely to take part in clinical trials in the future (Agree a lot; Agree a little; Neither agree nor disagree; Disagree a little; Disagree a lot; Don't know)
Q8: SHOWCARD – 'I'm now going to show you a list of statements and I'd like you to tell me to what extent you agree or disagree with each' A – It is important for everyone to take part in a randomised clinical trial if they are asked B – Taking part in clinical trials is as valuable to the NHS as giving blood C – I would take part in a randomised clinical trial if I was asked D – Taking part in clinical trials is only important if you are ill yourself E – I would recommend taking part in clinical trials to my friends and family if they asked me what I thought F – I am interested in finding out more about taking part in clinical trials (Agree a lot; Agree a little; Neither agree nor disagree; Disagree a little; Disagree a lot; Don't know)
Q9: SHOW TV ADVERT. Do you remember seeing this TV advert recently? Yes, No, Unsure, Refused
Q10: PLAY RADIO ADVERT. Do you remember hearing this advert recently? Yes, No, Unsure, Refused
Q11: SHOW PRESS IMAGE. Do you remember seeing this advert recently? Yes, No, Unsure, Refused
Q12: The advertising which I saw or heard made me more likely to take part in clinical trials in the future Yes, No, Unsure

However, on whether they would personally take part in a clinical trial if asked, there was little difference in response following the campaign [yes response 31.3% (95% CI 28.4, 34.1) vs. 30.4% (95% CI 27.6, 33.2), difference = -0.9%; 95% CI for difference -4.8, 3.1%; $P = 0.92$]. This nonsignificant difference was seen in both men and women and in all age groups.

When examples of the 'Get Randomised' advertising were shown or played to them, 29% of people recalled seeing the television advertisement (10% unsure), 20% hearing the radio advertisement (14% unsure) and 19% seeing the newspaper advertisement (15% unsure). Some people had seen more than one format of the advertisement.

The second survey finished by asking whether people agreed with the following statement: 'I would be more likely to participate in a clinical trial following this campaign'. The responses were 25% 'yes', 48% 'no' and 27% 'unsure'.

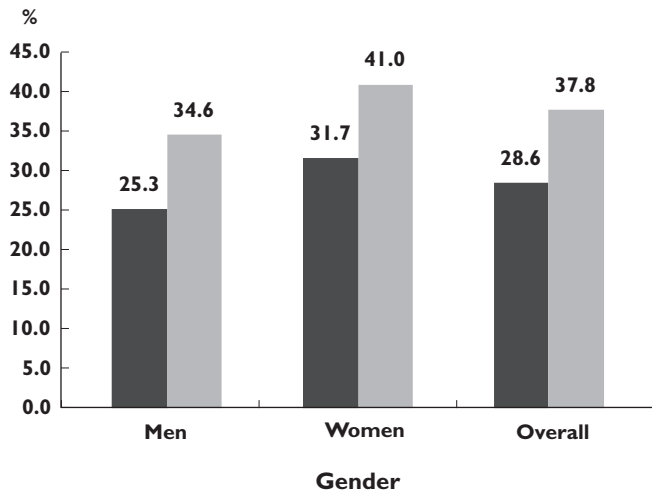


Figure 5

Percentage of men and women who had heard of the phrase 'randomised clinical trials' in Survey 1 (pre-campaign) and Survey 2 (post-campaign). Survey 1 (■); Survey 2 (□)

Discussion

The 'Get Randomised' campaign used a media-based approach to aim to increase public awareness and understanding of clinical research, ultimately improving public engagement in clinical research. Although the media have frequently been used to attract volunteers to specific studies, to the best of our knowledge a generic media campaign promoting the importance of clinical research has not previously been run in Scotland. It was hoped that a media-based campaign using different delivery methods would reach a large proportion of the population.

The campaign did indeed appear to raise public awareness of clinical trials (we observed an absolute increase in knowledge of the term of approximately 40% from before the campaign). This correlates well with the findings of previous mass media campaigns reported in the literature. For example, the Cochrane review of the impact of mass-media campaigns on healthcare utilization reported a consistent improvement in outcomes following campaigns [4]. Making comparisons with the commercial advertising industry, a campaign of this magnitude with relatively short advertisements and a comparatively limited budget may raise brand awareness but would not necessarily be expected to change consumer behaviour. Commercial advertising works over an extended period of time to raise brand awareness and build reputation. Consumers tend to

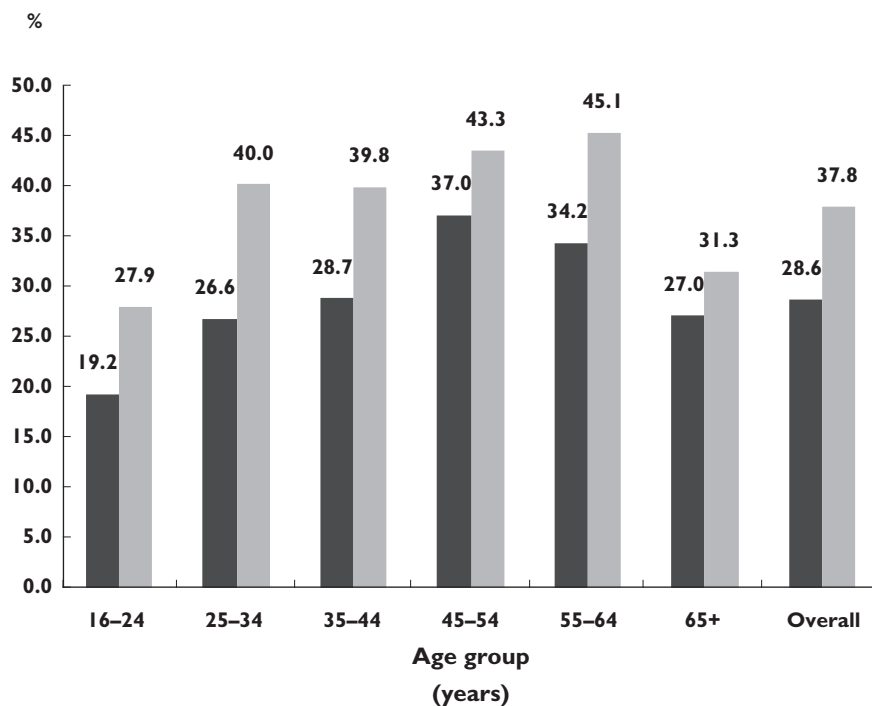


Figure 6

Percentage of people who had heard of the phrase 'randomised clinical trials' in the different age groups in Survey 1 (pre-campaign) and Survey 2 (post-campaign). Survey 1 (■); Survey 2 (□)

Table 3

Understanding of randomised clinical trials

Statement	Survey 1 August 2008 %	Survey 2 January 2009 %	Difference (95% CI) %	P-value
Clinical trials are needed to find out what treatments work	21.5	33.1	11.6 (4.9, 18.1)	<0.01
Clinical trials are needed to make medical progress	28.6	26.0	-2.6 (-9.4, 4.1)	0.44
Doctors decide on treatments based on the results of clinical trials	19.5	22.1	2.6 (-3.5, 8.7)	0.41
Taking part in clinical trials helps other people	11.4	24.4	13.0 (7.4, 18.6)	<0.01
Randomised clinical trials allocate treatments to participants by chance	18.5	17.6	-0.9 (-6.8, 4.8)	0.75
All age groups are needed to take part in clinical trials	4.7	16.5	11.8 (7.4, 16.2)	<0.01
Randomised clinical trials are required to study older treatments as well as newer treatments	5.7	13.7	8.0 (3.7, 12.3)	<0.01
To improve the health service we need information from clinical trials	9.8	13.5	3.7 (-1.1, 8.5)	0.14
Patients who take part in clinical trials generally have a good outcome	2.4	8.9	6.5 (3.2, 9.9)	<0.01
We all need treatment at some point and trials tell us about the best treatments	2.4	8.4	6.0 (2.8, 9.3)	<0.01
Don't know	7.1	13.0	5.9 (1.5, 10.3)	0.01

Patients were asked what 'randomised clinical trials' meant (Q2). Figures are percentages of respondents who expressed these statements. 95% confidence intervals are given for the differences in response between the two surveys.

change their behaviour later, for example to make a purchase, once the brand is already in their consciousness and trusted. Therefore, it may require further efforts before messages to the public regarding the importance of clinical trials result in increased participation in research.

'Get Randomised' was chosen to be the central message of the campaign. RCTs are widely regarded as being the gold-standard method of assessing differences between treatment options. Most clinical research in the UK is conducted on an 'opt-in' basis rather than an 'opt-out' basis, largely due to ethical considerations. An 'opt-in' approach often selects out a healthier than average study population who take more interest in their health in general and are therefore more likely to volunteer to take part in research. Unfortunately, this can result in recruitment of a nonrepresentative population to many research studies [5]. This could be particularly important in some types of research where end-points are outcomes such as cardiovascular disease or smoking-related disease, which are known to correlate with illness behaviours and social deprivation status. Conversely, in other situations patients with particular diseases or those who feel that they may benefit from a new or expensive drug that is not otherwise available outside the clinical trial setting may be more likely to participate in clinical trials. Indeed, organizations such as the European Platform for Patients' Organizations, Science and Industry (<http://www.epposi.org>) support patient participation in clinical trials and have expressed concern at recent meetings that the European Clinical Trials Directive may adversely affect entry into clinical trials. UK researchers have also expressed concern that increased bureaucracy has made clinical trials more administratively cumbersome and expensive [6]. It is important to encourage all sectors of society to understand more about clinical research and to feel that they are able to take part in it. Using the media may help to bring

the message that clinical research is important to sectors of the population who are more difficult to reach by standard methods such as lengthy invitation letters and information sheets for individual studies.

In most research studies, invitations to patients to participate result in a significant nonresponse rate. In our experience this varies, but is often around 50% and is accompanied by a refusal rate of another 25%, leaving only 25% of the original population approached potentially willing to be recruited to the study. On further screening, some of the patients initially selected may be excluded for other reasons, resulting in a much diminished population who actually enter the treatment arm of a study [in our recent experience in recruiting to a large RCT only 14% of the originally identified suitable population are eventually randomised to therapy (clinicaltrials.gov – NCT00447759)]. Some trials experience even lower response rates.

Successful recruitment to clinical research studies relies heavily on improving the proportion of patients initially responding positively to an invitation to participate. Despite this, the reasons for nonresponse and refusal are still poorly understood. Some of the factors leading to patients failing to respond or refusing to take part in research may include failure to receive or understand the letter or information sheet, failure to feel that the research applies to them as individuals, feelings that they would not be of interest to the researchers, apathy, lack of time due to other commitments and feelings of invasion of privacy [7]. More specifically, in RCTs, some people fail to understand the concept of randomisation [8] and may prefer treatment to be allocated by conscious decision as occurs in normal care. There is some, albeit limited, evidence that patients who participate in clinical trials may have better outcomes [9], and in other recent meta-analyses there is no evidence of a harmful effect of participating in clinical trials and if anything there is a trend towards benefit

[10, 11]. There are limited data on which strategies to increase recruitment into clinical trials are successful and further investigation into this area is needed [12, 13].

Conclusions

Public awareness and understanding of clinical research is key to ensuring adequate recruitment to clinical research trials. This media-based campaign was successful in its primary aim of raising public awareness of clinical research in Scotland. Although the post-campaign survey revealed an increase in understanding of some aspects of clinical trials, there was no apparent significant increase in the individual willingness of members of the public to participate in clinical research studies. Therefore, the campaign may have been better at raising public awareness of research than convincing the public to participate personally in research trials. However, this might be the first stage in increasing public participation in clinical trials. Whether the campaign will increase public participation in clinical research in the long term will require further evaluation. Perhaps a concerted national effort is needed to improve public engagement and continue to raise awareness of the importance of clinical research.

Competing interests

None to declare.

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